

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON**

ANGELA K. PARKER,

Plaintiff,

v.

**ORTHOFIX INC. and ORTHOFIX
HOLDINGS, INC.,**

Defendants.

Case No. 3:17-cv-248-SI

OPINION AND ORDER

William J. Macke, WILLIAM MACKE & ASSOCIATES, 4411 NE Tillamook Street,
Portland, OR 97213. Of Attorneys for Plaintiff.

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Suite 200, Portland, OR 97204. Of Attorneys for Defendants.

Michael H. Simon, District Judge.

Angela K. Parker asserts a claim of negligence against Orthofix Inc. and Orthofix Holdings, Inc. (collectively, “Defendant”). Defendant manufactures medical implants. In her Complaint, Plaintiff alleges that Defendant was negligent in two respects: (1) by negligently providing inaccurate information to Plaintiff’s surgical team before Plaintiff’s second unsuccessful surgery; and (2) by negligently manufacturing a medical device with a known and

safer option. After Defendant moved for summary judgment against both theories of negligence, Plaintiff conceded her second theory, alleging negligent product design. Accordingly, all that remains before the Court is Plaintiff's first theory, alleging negligent misrepresentation resulting in personal injury. For the reasons that follow, Defendant's motion for summary judgment is granted.

STANDARDS

A. Summary Judgment Generally

A party is entitled to summary judgment if the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the burden of establishing the absence of a genuine dispute of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in the non-movant's favor. *Clicks Billiards Inc. v. Sixshooters Inc.*, 251 F.3d 1252, 1257 (9th Cir. 2001). "Where the non-moving party bears the burden of proof at trial," however, "the moving party need only prove that there is an absence of evidence to support the non-moving party's case." *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387 (9th Cir. 2010). Thereafter, the non-moving party bears the burden of designating "specific facts demonstrating the existence of genuine issues for trial." *Id.* "This burden is not a light one." *Id.* The Supreme Court has directed that in such a situation, the non-moving party must do more than raise a "metaphysical doubt" as to the material facts at issue. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Furthermore, the "mere existence of a scintilla of evidence in support of the plaintiff's position [is] insufficient" *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 255 (1986).

B. Evidence Considered at Summary Judgment

In evaluating the nonmoving party's facts offered at summary judgment, the Court does "not focus on the admissibility of the evidence's form. [The Court] instead focus[es] on the admissibility of its content." *Fraser v. Goodale*, 342 F.3d 1032, 1036 (9th Cir. 2003); *see also Celotex*, 477 U.S. at 324 ("We do not mean that the nonmoving party must produce evidence in a form that would be admissible at trial in order to avoid summary judgment."). At summary judgment, the Court may consider "evidence submitted in an inadmissible form, so long as the underlying evidence could be provided in an admissible form at trial, such as by live testimony." *JL Beverage Co., LLC v. Jim Beam Brands Co.*, 828 F.3d 1098, 1110 (9th Cir. 2016) "Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial." *Matsushita*, 475 U.S. at 587 (citation and quotation marks omitted); *see also Norse v. City of Santa Cruz*, 629 F.3d 966, 973 (9th Cir. 2010); *Burch v. Regents of Univ. of Cal.*, 433 F. Supp. 2d 1110, 1120 (E.D. Cal. 2006); *cf. Fed. R. Civ. P.* 56(c)(2) (permitting a party to "object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence"). For example, in *Fraser* the Ninth Circuit considered a diary's contents as evidence to defeat a motion of summary judgment, despite a hearsay challenge, because the contents of the diary "could be admitted into evidence at trial in a variety of ways," including that the witness "could testify to all the relevant portions of the diary from her personal knowledge." *Fraser*, 342 F.3d at 1037. "Because the diary's contents could be presented in an admissible form at trial, we may consider the diary's contents in the [movant's] summary judgment motion." *Id.*

BACKGROUND

In 2013, Plaintiff had surgery to decompress and fuse vertebrae in her neck in an attempt to relieve her back and neck pain. As part of this procedure, the surgeon implanted Defendant's

Hallmark Anterior Cervical Plating System (the “Orthofix Plate”), a metal implant used to facilitate neck vertebrae fusion. Plaintiff’s pain, however, continued after her 2013 surgery, and her physicians referred Plaintiff to Dr. Richard S. Polin, a neurosurgeon. Dr. Polin determined that some of the fusions from Plaintiff’s 2013 surgery had failed and that Plaintiff would need a second surgery to fix the earlier fusions and fuse additional vertebrae. Dr. Polin planned to remove the Orthofix Plate, perform the decompression and fusion procedure, and reinstall a new plate made by Aesculap, a different manufacturer of medical devices.

The second surgery also was unsuccessful. In fact, it could not be completed. The surgical team placed Plaintiff under general anesthesia and made the necessary incisions. As Dr. Polin prepared to remove the Orthofix Plate, he discovered that he lacked the correct “impact driver bit,” which is a specialized tool needed to remove the locking screws on the Orthofix Plate. To remove these locking screws requires a tri-lobed driver bit. The standard “universal tray” of surgical tools found in the operating room included only square and hexagonal driver bits, not the needed tri-lobed driver bit. During the procedure, the surgical team called Defendant and spoke with one of Defendant’s employees, who confirmed that the driver bits in the hospital’s universal tray could not remove the Orthofix Plate. Dr. Polin decided to terminate the surgical procedure and leave the Orthofix Plate temporarily in place. Plaintiff then needed a third surgery to complete Dr. Polin’s planned procedure with the appropriate tools.

Defendant and other medical device manufacturers regularly provide, upon request, trays of specialized tools that a surgeon will need to implant or remove the manufacturer’s devices. Hospitals routinely request these tools from a manufacturer’s local sales representative, who may be an independent contractor. The local sales representative then acquires any needed specialized

tools from the manufacturer, delivers the tools to the hospital at least 24 hours in advance of the surgery, and often attends the surgery.

Dr. Polin performed Plaintiff's second surgery at the Providence Portland Medical Center ("Providence"). That hospital has a supply office responsible for ordering specialized surgical tools after a surgeon either requests those tools or notes that an upcoming surgery will involve installing or removing medical implants. Providence requires that any necessary surgical tools be delivered to the hospital at least 24 hours before a scheduled surgery.

According to its records, Providence never received Defendant's specialized tri-lobed driver bit, which was necessary to remove the Orthofix Plate, before Plaintiff's second surgery. The parties dispute the reason for the absence of the needed driver bit from the operating room. According to Plaintiff, Defendant inaccurately told Providence that the universal tray of surgical tools already on hand would be able to remove the Orthofix Plate, and Providence accordingly did not request any specialized driver bits. Defendant responds that it never provided any such information and presumes that everyone on the surgical team must have incorrectly believed that someone else would contact Defendant to obtain the specialized tool. Unfortunately for Plaintiff, no one did.

During discovery, the parties questioned several people involved in Plaintiff's unsuccessful surgery. Gail Mastrandrea, Providence's clinical supervisor, testified that she never requested the specialized driver bit from Defendant, in part because Dr. Polin never noted in his pre-surgery report that he intended to remove an existing medical implant. Mastrandrea further testified that she had no contact with Defendant before the unsuccessful surgery. Dr. Polin noted in a post-surgery report that he believed that someone had contacted Defendant to secure the necessary specialized tool and that someone affiliated with Defendant told that person that the

hospital's universal tray would contain the tool needed to remove the Orthofix Plate. In his deposition testimony, Dr. Polin confirmed this second-hand account contained in his post-surgery report, although he could not provide any further details or corroboration. Dr. Polin also mentioned that he may have spoken to a sales representative for Aesculap (one of Defendant's competitors), who may have told him that a universal tool kit would contain a tool sufficient to remove the Orthofix Plate.

The Aesculap sales representative, however, denied ever communicating this information to Dr. Polin and denied communicating with Defendant before Plaintiff's unsuccessful surgery. Dr. Polin also testified that he did not personally communicate with Defendant before the surgery. In addition, Defendant's employees have no record of anyone from Defendant communicating with *anyone* about Plaintiff before Defendant received the telephone call *during* the unsuccessful surgery.

Plaintiff later underwent a third surgery, with the surgical team using the correct specialized tool. That surgery resulted in the successful removal of the Orthofix Plate and the installation of a new plate from Aesculap. Plaintiff, however, continues to suffer pain. After the more recent surgery, Plaintiff brought this action, alleging that Defendant negligently misinformed Providence and the surgical team before the unsuccessful surgery about the tool needed to remove the Orthofix Plate being contained within a universal tray of operating tools. According to Plaintiff, this misinformation caused the surgical team to begin operating on Plaintiff without having the correct tool, resulting in the surgical team needing to abandon that surgery and requiring an additional surgery. Plaintiff has not asserted any claims against either Providence or the surgical team, including Dr. Polin. Specifically, Plaintiff has not asserted a claim against Dr. Polin based on his failure to note in a pre-surgery report that he intended to

remove an existing medical implant, which would have triggered a response by the hospital's supply office.

DISCUSSION

In its motion for summary judgment, Defendant argues that, among other things, Plaintiff's evidence contains at least one level of inadmissible hearsay and that without that hearsay Plaintiff cannot prevail on her claim of negligent representation against Defendant. In response, Plaintiff argues that she expects that she will be able to present at trial sufficient admissible evidence to support her claim, although Plaintiff does not identify any particular witness who can support that claim. Defendant challenges Plaintiff's ability to support that claim with evidence that will be admissible at trial.

A. Dr. Polin's Notes

Plaintiff offers Dr. Polin's surgical and post-surgical notes to show that someone associated with Defendant provided incorrect information to Providence. In a post-surgery note by Dr. Polin written on the day of Plaintiff's unsuccessful surgery, Dr. Polin stated that, before the procedure, "We called Orthofix to get the trays send [sic] over to remove the system, but according to the facility they said that the screws could be removed by universal system." ECF 31, at 34. Further, in a note by Dr. Polin written one week after the unsuccessful surgery, he explained that "[i]ntra-operatively we could not remove the Orthofix plate because that company told us that a universal tray would remove their hardware but unfortunately it would not." ECF 31, at 21.

Defendant argues that Dr. Polin's notes are inadmissible because they are or contain hearsay. Plaintiff responds that these notes fall within several hearsay exceptions, including the business-records exception. *See* Fed. R. Evid. 803(6). Defendant replies that even if Plaintiff is correct and the business-records exception applies to the documents themselves, that exception

addresses only the first layer of hearsay in Plaintiff's documentary evidence and that the contents of the notes contain inadmissible hearsay. *See* Fed. R. Evid. 805.

Hearsay is a statement that the declarant does not make while testifying at the current trial or hearing and that a party offers in evidence to prove the truth of the matter asserted in the statement. *See* Fed. R. Evid. 801(c); *see also Calmat Co. v. U.S. Dep't of Labor*, 364 F.3d 1117, 1123 (9th Cir. 2004). Dr. Polin's notes reflect the following three layers of potential hearsay: (1) the notes themselves are unsworn, out-of-court statements by Dr. Polin; (2) the notes also contain references to unsworn, out-of-court statements purportedly made by other unidentified members of the surgical team; and (3) the statements of these unknown persons further describe additional unsworn, out-of-court statements supposedly made by unidentified employees or agents of Defendant. The first inquiry is whether an exception applies to each of these three layers of hearsay. Fed. R. Evid. 805.

Regarding the first layer of hearsay, Plaintiff is correct that the exception provided in Fed. R. Evid. 803(6) generally makes Dr. Polin's notes, being medical records, admissible as business records. *See United States v. Hall*, 419 F.3d 980, 987 (9th Cir. 2005) ("The medical records . . . were records kept in the ordinary course of business, classic exceptions to the hearsay rule."); *Manocchio v. Moran*, 919 F.2d 770, 780 (1st Cir. 1990) ("[M]edical records are themselves independently admissible under the business records exception, a 'firmly rooted' exception to the hearsay rule."). Under Fed. R. Evid. 803(6), the business-records exception, hearsay evidence is nevertheless admissible if:

- (A) the record was made at or near the time by—or from information transmitted by—someone with knowledge;
- (B) the record was kept in the course of a regularly conducted activity of a business . . .
- (C) making the record was a regular practice of that activity;

(D) all these conditions are shown by the testimony of the custodian or another qualified witness . . . and

(E) the opponent does not show that the source of information or the method or circumstances of preparation indicate a lack of trustworthiness.

Fed. R. Evid. 803(6).

First, one note was written on the day of surgery and the other was written a week after surgery. In addition to describing the surgeries, the medical notes refer to communications purportedly with Defendant. The notes do not mention when these alleged communications supposedly occurred or who was involved, but a rough chronology may be reasonably inferred. Because hospitals generally need to receive specialized tools no later than 24 hours before surgery, it follows that a communication with a medical implant manufacturer like Defendant would likely occur, if at all, at some reasonable time before surgery but not substantially before the date of surgery. The Court is satisfied that notes themselves were made reasonably near the time of the events they describe. *Compare Wheeler v. Sims*, 951 F.2d 796, 804 (7th Cir. 1992) (11-day-old record was sufficiently contemporaneous), *with Willco Kuwait (Trading) S.A.K. v. deSavary*, 843 F.2d 618, 628 (1st Cir. 1988) (three-month-old telex was not “at or near the time” of events described).

Second, the medical notes were kept in the course of surgery and patient consultation, both regularly conducted activities for a doctor. Third, it appears that note-taking is a regular practice associated with those medical activities. For example, Dr. Polin wrote the notes using a standardized format. ECF 31, at 29-36. Similarly, the notes match other treatment notes with consistent formatting, ranging from November 11, 2014, to July 14, 2015. ECF 31, at 14-18. The uniformity and regularity of these notes suggest that Dr. Polin wrote them as part of a regular note-keeping practice.

Fourth, Dr. Polin could testify at trial to confirm that the first three requirements of the business-records exception, outlined above, are met in this case. Finally, Defendant has not argued that the medical notes or the circumstances of their preparation indicate a lack of trustworthiness. Accordingly, Dr. Polin's medical notes, although hearsay, would be admissible under the business-records exception generally. The difficult issue for Plaintiff, however, is finding an exception for the second and third layers of apparent hearsay. For the notes to be admissible, each layer of hearsay must qualify for an exception. *See* Fed. R. Evid. 805; *Sana v. Hawaiian Cruises, Ltd.*, 181 F.3d 1041, 1045 (9th Cir. 1999).

The third level of hearsay in the notes reflects that someone on Dr. Polin's surgical team may have spoken with someone affiliated with Defendant and that the Defendant's representative made the allegedly liability-creating statements. Under the Federal Rules of Evidence, a statement of an opposing party is not hearsay. Fed. R. Evid. 801(d)(2). When an organization is the party, however, the proponent generally must establish that the statement either "was made by a person whom the party authorized to make a statement on the subject" or "was made by the party's agent or employee on a matter within the scope of that relationship and while it existed." Fed. R. Evid. 801(d)(2)(C), (D). Plaintiff, however, does not know who among Defendant's agents or employees made the liability-creating statement and thus may face some difficulty presenting admissible evidence at trial that the statement was actually made. Perhaps Plaintiff could surmount this problem with reasonable inferences. In the alternative, perhaps Plaintiff could surmount this problem with the argument that the statement by Defendant is not hearsay because it is not being offered for the truth of the matter asserted. Fed. R. Evid. 801(a)(c)(2). In fact, the significance to Plaintiff's case is that the statement from Defendant turned out not to be true. Plaintiff, however, has a more difficult problem to overcome.

The second level of hearsay in Dr. Polin's notes reflects that someone on his surgical team (or perhaps at Providence—but not a party opponent) told Dr. Polin about a conversation that person supposedly had with Defendant. That statement is offered for the truth of the matter asserted. First, it is being offered for the truth that the underlying conversation took place with a representative of Defendant, as opposed for example with a representative of Aesculap, Defendant's competitor. Second, it is being offered for the truth of what that representative supposedly said about whether a tool on a universal tray would be sufficient to do the job needed. Thus, there must be a hearsay exception for this second level.

Plaintiff, however, does not even know who made this statement to Dr. Polin, which is the second level of hearsay. Plaintiff also has completed discovery and represented to the Court that further discovery would not be likely to reveal the identity of that person. Because that person is not a party opponent, Plaintiff would need a hearsay exception for that second level of hearsay offered for the truth of the matter stated. Plaintiff has not offered a viable hearsay exception, and none appears to the Court. Thus, Dr. Polin's notes are not sufficient to create a genuine issue for trial.

B. Plaintiff's Deposition Evidence

In addition to Dr. Polin's notes, Plaintiff also offers certain deposition testimony as evidence of Defendant's alleged misrepresentations. Dr. Polin testified in deposition about his second-hand knowledge of a conversation supposedly with Defendant. Mr. Polin testified: "I can remember in this case *someone telling me that they had talked to Orthofix*, and . . . saying that . . . the plate was easy to take out . . . with what I believe is called a universal system." ECF 31, at 3 (emphasis added). Dr. Polin further testified that, "I remember several independent conversations with the [Aesculap local sales representative], telling me that they were calling Orthofix . . . [and that the Orthofix Plate] will come out with standard universal instrumentation

removal sets.” ECF 31, at 4. In short, Dr. Polin testified that others on the surgical team or perhaps a representative of Defendant’s competitor Aesculap told Dr. Polin that *they* had spoken to Defendant. Dr. Polin, however, was not present for that conversation with Defendant. *Id.* Thus, Dr. Polin’s testimony contains the same problem of multiple hearsay as do his notes. If Plaintiff had a witness who could testify at trial that this witness spoke with an agent or employee of Defendant, that might be sufficient. But there is no reason to believe that such a witness can be identified or located. Dr. Polin’s anticipated testimony at trial that he was told by someone other than Defendant that that person spoke with Defendant is inadmissible hearsay, as discussed above.

Plaintiff also characterizes Dr. Polin’s deposition testimony as describing a telephone call with Defendant *during* Dr. Polin’s unsuccessful surgery. According to Plaintiff, Dr. Polin testified that during that unsuccessful surgery Dr. Polin heard an employee of Defendant state over the telephone that the universal tray would remove the Orthofix Plate. Plaintiff supports this characterization of Dr. Polin’s testimony with citations to specific sections of the deposition transcript. Dr. Polin’s actual testimony in these sections, however, refers only to conversations that Dr. Polin heard about second-hand *before* the surgery. ECF 31, at 4-5. Further, even if Plaintiff’s characterization of the evidence were correct, such evidence would still be insufficient.

Plaintiff’s negligence claim alleges that Defendant misrepresented the tools required to remove the Orthofix Plate, which in turn caused the surgical team to begin Plaintiff’s unsuccessful surgery without the necessary tools. Because Plaintiff alleges that Defendant supposedly gave this misinformation to the surgical team *before* surgery, evidence of a statement made by an employee or agent of Defendant *during* the unsuccessful surgery would not provide

support for Plaintiff's claim or create a genuine dispute of material fact. By that time, the surgery had begun and any misstatements made during that surgery cannot be the cause of that surgery having occurred.

Plaintiff also presents testimony that Dr. Polin asked an employee of Defendant, *during the unsuccessful surgery*, why the specialized tools were never sent to Providence. Dr. Polin testified that Defendant's employee offered an unsatisfactory explanation. ECF 31, at 11. That employee's inability to explain the situation is understandable. The employee appears to have known that the Orthofix Plate required a specialized tool to remove the plate, and thus was confused to hear that Providence had not obtained the necessary tool before surgery. Defendant's employee appears not to have known why the operating room lacked the specialized tool. There is no probative value to this evidence, and it does not create a genuine issue of fact whether Defendant made the alleged misrepresentations *before* the unsuccessful surgery.

Further, Plaintiff offers the testimony of an Aesculap sales representative, Stacey Hamm. Plaintiff characterizes Hamm's testimony as supporting Plaintiff's assertion that an employee of Defendant told the surgical team *during* the unsuccessful surgery that the universal tray contained a tool that could remove the Orthofix Plate. Plaintiff also characterizes Hamm's testimony as supporting the proposition that Hamm also heard from Dr. Polin before the surgery that someone on Dr. Polin's team had spoken to Defendant and that an agent or employee of Defendant had claimed that the universal tray contained a tool that could remove the Orthofix Plate.

Plaintiff's reliance on Hamm's testimony for the first proposition is unhelpful. Hamm clarified in his testimony that Defendant's employee told the surgical team only about which specialized tool was needed to remove the Orthofix Plate and what methods could be used to

remove the Orthofix Plate without the proper tools using only tools available on the universal tray. ECF 22, Ex. 6, at 2-3. Further, as with Dr. Polin's testimony, evidence describing the actions of Defendant's employees *during* the unsuccessful surgery does not create a genuine dispute of material fact regarding Plaintiff's claim that Defendant negligently misinformed Providence *before* the unsuccessful surgery.

Plaintiff's reliance on Hamm's testimony as evidence that Dr. Polin believed that Defendant had told someone that the universal tray contains a tool sufficient to remove the Orthofix Plate also is insufficient. Hamm testified, "I had spoken with Dr. Polin and it was his understanding that we would only need the universal system . . . he thought the hospital had contacted the Orthofix rep to get the product there." ECF 31, at 39. Hamm's testimony on this point contains a middle level of hearsay for which an exception is needed but none appears to be available.

Finally, Hamm testified that Dr. Polin may have told Hamm that Dr. Polin had spoken directly with Defendant. Dr. Polin, however, testified that he never spoke with Defendant and in fact believed that Hamm had been the person who spoke with Defendant. This hearsay also is insufficient to create a genuine issue for trial.

The final question to consider is whether Plaintiff can present admissible evidence at trial that is sufficient to withstand a motion for judgment as a matter of law. Based upon Plaintiff's responses to Defendant's motion, it does not appear that Plaintiff can do so. The Court accepts that Plaintiff has been injured through no fault of her own. Indeed, someone dropped the ball, which caused Plaintiff to have to undergo an additional surgery. Whether that someone was Dr. Polin, someone on his surgical team, someone working for Providence, someone working for Defendant, or someone else, the Court cannot determine, and on the evidence presented by

Plaintiff neither can a jury. Because Plaintiff's only claim before the Court is against Defendant and because Plaintiff has not created a genuine issue of fact, summary judgment in favor of Defendant must be granted.

CONCLUSION

Defendant's motion for summary judgment (ECF 20) is GRANTED.

IT IS SO ORDERED.

DATED this 14th day of February, 2019.

/s/ Michael H. Simon
Michael H. Simon
United States District Judge